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**Summary of Safety and Effectiveness**

**Smith & Nephew Orthopaedics**

**Revision Hip System -**

The Revision Hip System stems are single use devices. The components are indicated for cemented and uncemented use for individuals undergoing primary and revision surgery where other treatments or devices have failed for rehabilitating hips damaged as a result of trauma, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Indications also include inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

The components of the Revision Hip System have the same function as other hip systems designed for cemented and cementless fixation.

The engineering analyses of these devices was acceptable and the components of the Revision Hip System should perform as well as other hip systems.